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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,177	06/01/2005	Paivi Juujarvi	TUR-169	7986
32954	7590	10/25/2006	EXAMINER	
JAMES C. LYDON 100 DAINGERFIELD ROAD SUITE 100 ALEXANDRIA, VA 22314			CHENG, KAREN	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/537,177	Applicant(s) JUJARVI ET AL.	
	Examiner Karen Cheng	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/1/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-12 are currently pending in the instant application.

Information Disclosure Statement

Applicant's Information Disclosure Statement: filed on June 1, 2005 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Priority

The application is a 371 of International Application No. PCT/FI04/00004, filed on 1/08/2004, which claims the benefit of foreign priority under 35 U.S.C. 119, to Finish Application No. 20030026, filed on 01/08/2003. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Finland on 01/08/2003. It is noted, however, that applicant has not provided an English translation of the document as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of an amine of formula R_4NH_2 wherein R_4 is benzyl does not reasonably provide enablement for use of an amine of formula R_4NH_2

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wherein R_4 can be other leaving groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to utilize the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention comprises the process of reacting a compound of formula (III) with an amine of formula R_4NH_2 wherein R_4 is defined as an easily removable leaving group.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that there is wide range of leaving groups, and “easily removable leaving groups” are not well defined according to the specification. The existence of these obstacles establishes that one of ordinary skill in the art would not

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know what chemical structures are encompassed by the term "easily removable leaving group." In the instant case, the specification does not provide guidance as to how one skilled in the art would ascertain what would be considered an easily removable leaving group as the example provided cites phenyl as an "easily removable leaving group", which would not be considered an easily removable leaving group to one of ordinary skill in the art. The specification fails to enable one of ordinary skill in the art to have sufficient direction to determine what could be considered an "easily removable leaving group."

The amount of direction or guidance present and the presence or absence of working examples

The specification gives an example of the use of phenylamine as an amine of formula R_4NH_2 . However, no indication of the use of a common leaving group such as a halogen, acetates, etc is provided.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include R_4NH_2 where R_4 is defined as an easily removable leaving group but the specification only provides evidence for the use of a compound where R_4 is phenyl, a group which would not be considered an easily removable leaving group by one of ordinary skill in the art.

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain what could be considered an easily removable leaving group. Factors such

as "sufficient working examples", "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant process claims. In view of the breadth of the claims, the chemical nature of the invention and the lack of working examples regarding the process as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

In consideration of each of the 8 factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Therefore, claims 1-12 are rejected under 35 U.S.C. § 112, 1st paragraph.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "derivative" of the compounds of Claim 1 is not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-7. It is suggested the claim 1 be amended to "a process for preparing compounds of formula (I) and acid addition salts thereof" in order to overcome this rejection.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-12 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1-12 are drawn to a process that uses compounds possessing an easily removable leaving group. However, the "easily removable leaving group" of the compounds of Claims 1-12 is not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claim 1 is drawn to a process for preparing substituted imidazole derivatives of formula (I). However, the "derivatives" of the compounds of Claim 1 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

It is suggested the claim 1 be amended to "a process for preparing compounds of formula (I) and acid addition salts thereof" in order to overcome these rejection.

Claim Objections

Claim 1 is objected to because of the following informalities. It defines Y as a formula: "in which formula Y is $-\text{CH}_2-$ or $-\text{CO}-$ " in a case where Y would not be

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considered a formula. Applicant is advised to delete the word formula. Appropriate correction is required.

Objections: Content of Specification

The specification does not incorporate cross reference to related applications.

The specification should contain the following sections below, as applicable:

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of

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the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

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There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Conclusion

A search was made of the prior art, and the closest art was found in US Patent No. 5,292,887 whereby compounds of formula (I) and the process of preparation are disclosed. The process disclosed does not use an alkali metal thiocyanate but an amide group to form the imidazole, and thus the resulting product does not contain a mercapto group.

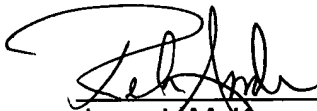
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cheng
Patent Examiner, AU 1626



Joseph McKane
Supervisory Patent Examiner, AU 1626

REBECCA ANDERSON
PATENT EXAMINER